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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,173	08/31/2001	Rachel Meyers	381552003500	3164

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Intellectual Property Group  
MILLENNIUM PHARMACEUTICALS, INC.  
75 Sidney Street  
Cambridge, MA 02139

EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/945,173

Applicant(s)

MEYERS, RACHEL

Examiner

J. Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Claims 1-24 are pending in the application and addressed herein.

#### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-3 and 6, drawn to a nucleic acid and host cell comprising the nucleic acid, classified in class 435, subclass 325.
  - II. Claim 4, drawn to an isolated polypeptide, classified in class 530, subclass 350.
  - III. Claim 5, drawn to an antibody, classified in class 580, subclass 387.1.
  - IV. Claim 7, drawn to a method for detecting the presence of a nucleic acid, classified in class 435, subclass 6.
  - V. Claim 8, drawn to a kit comprising a compound which binds to a nucleic acid or protein, classified in class 536, subclass 24.33.
  - VI. Claim 9, drawn to a method for identifying a compound which binds to and modulates activity of a polypeptide, classified in class 435, subclass 6.
  - VII. Claim 10, drawn to a method for modulating the activity of a polypeptide, classified in class 435, subclass 6.
  - VIII. Claims 11, 12, 14 and 15, drawn to a method to identify a nucleic acid associated with a disorder, classified in class 435, subclass 6.
  - IX. Claims 13 and 16, drawn to a method for identifying a polypeptide associated with a disorder, classified in class 435, subclass 6.
  - X. Claim 17, drawn to a method to identify a therapeutic compound, classified in class 435, subclass 6.

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XI-XXI. Claims 19 and 20 drawn a method of treating a disorder wherein the disorder is:  
[all in class 435, subclass 6]

- XI. cancer
- XII. aberrant cellular proliferation
- XIII. aberrant differentiation
- XIV. cardiovascular disorder
- XV. liver disorder
- XVI. pain
- XVII. metabolic disorder
- XVIII. brain disorder
- XIX. blood vessel disorder
- XX. hematopoietic disorder
- XXI. platelet disorder

Upon election of any of Groups XI-XXI, further group election is required of one (1) of the following patently distinct subgroups:

- A. Claim 19 as it is drawn to a method of treatment using a small molecule, classified in class 514, subclass 1.
- B. Claim 19 as it is drawn to a method of treatment using a peptide, classified in class 514, subclass 2.
- C. Claim 19 as it is drawn to a method of treatment using a phosphopeptide, classified in class 514, subclass 2.
- D. Claim 19 as it is drawn to a method of treatment using an antibody, classified in class 424, subclass 130.1.
- E. Claim 19 as it is drawn to a method of treatment using a polypeptide, classified in class 514, subclass 2.
- F. Claim 20 as it is drawn to a method for treatment using an antisense molecule, classified in class 514, subclass 44.

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G. Claim 20 as it is drawn to a method for treatment using a ribozyme, classified in class 514, subclass 44.

H. Claim 20 as it is drawn to a method for treatment using a polynucleotide, classified in class 514, subclass 44.

XXII. Claim 21, drawn to a method to evaluate the efficacy of a treatment, classified in class 435, subclass 6.

XXIII. Claim 22, drawn to a method for diagnosing a disorder, classified in class 435, subclass 6.

Claims 18, 23 and 24 link(s) the inventions of Groups XI-XXI (and A-H). The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different products which are chemically, structurally and functionally different.
3. Inventions IV, VI-XXI (and A-H) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together or they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods which require different materials, have different method steps and/or have different modes of operation, different functions, or different effects.
4. Inventions I and XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid can be used in many materially different processes. For instance the nucleic acid of Group I can be used in hybridization assays, templates for PCR reactions, or to express the encoded polypeptide in vitro or in vivo.
5. Inventions II and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case the polypeptide of Group II can be used in many materially different processes. For instance the polypeptide can be used to generate antibodies or as a molecular weight marker protein in gel electrophoresis assays.

6. Inventions III and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the antibody of Group III can be used in many materially different processes. For instance, the antibody can be used in immunoblot assays, as well as immunopurification assays.

7. Inventions I and II are unrelated to inventions IV, VI-XIII and XV-XX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions IV, VI-XIII and XV-XX are drawn to methods which do not require the nucleic acid or polypeptide of inventions I and II.

8. Inventions II and III are unrelated to inventions IV, VI-XVII and XIX-XX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of inventions IV, VI-XVII and XIX-XX do not require the polypeptide or antibody of Inventions II and III.

9. Inventions I and III are unrelated to inventions IV, VI-XIV and XVI-XX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

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different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of inventions IV, VI-XIV and XVI-XX do not require the nucleic acid or antibody of Inventions I and III.

10. Invention V is unrelated to inventions IV, and VI-XX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of inventions IV, VI-XX do not require the kit of Invention V.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

12. Because these inventions are distinct for the reasons given above and the search required for each Group is not required for the other Groups (i.e., the searches are not coextensive), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the



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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell  
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DAVET. NGUYEN  
PRIMARY EXAMINER